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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,948	10/28/2005	Peter Frank Ekhart	0470-050777	7559
7590 11/05/2009 Webb Ziesenheim Logsdon Orkin & Hanson 436 Seventh Avenue 700 Koppers Building Pittsburgh, PA 15219-1818				
EXAMINER				
BLAND, LAYLA D				
ART UNIT		PAPER NUMBER		
1623				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/526,948

**Applicant(s)**

EKHART ET AL.

**Examiner**

LAYLA BLAND

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 15-27, 29 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 15-27, 29 and 32-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is a response to Applicant's amendment submitted August 27, 2009, wherein claims 13, 19, 21, 27, 29, 33, 34, 37, 40, 44, and 45 are amended.

Claims 13, 15-27, 29, and 32-46 are pending and are examined on the merits herein.

The following new rejections were necessitated by Applicant's amendment submitted August 27, 2009, wherein the limitation "wherein the food composition has a texture that remains substantially unchanged by adding the  $\alpha$ -glucan until the food composition enters a stomach of a person" was added to claims 13, 19, 27, 29, 33, 34, and 37.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-27, 29, and 32-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were amended to recite "wherein the food composition has a texture that remains

substantially unchanged by adding the  $\alpha$ -glucan until the food composition enters a stomach of a person.” The examiner was unable to locate support for this limitation in the disclosure as filed. The specification teaches a number of food products, but does not describe a food product having a texture that remains substantially unchanged by addition of  $\alpha$ -glucan. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15-27, 29, and 32-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “wherein the food composition has a texture that remains substantially unchanged by adding the  $\alpha$ -glucan until the food composition enters a stomach of a person.” This is a functional limitation, and it is unclear which foods meet the limitation, and at which concentration of glucan. While describing a product in terms of its function is not itself improper (see *In re Swinehart*, 439 F.2d 210, 169USPQ 226 (CCPA 1971)), claims directed to a product should be distinguished from the prior art product in terms of structure rather than function; this point was recently revisited. “When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area). We note that the patent drafter is in the best

position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation." *Halliburton Energy Services, Inc. v. M-I LLC*, 85 USPQ2d 1654, 1663 (Fed. Cir. 2008). Such ambiguity could be resolved in a few ways, for example by providing a quantitative metric for the property, or a formula for calculating the claimed functional property along with examples and counterexamples of products with that property. Claims that are ambiguous as to boundaries for functional limitations may be indefinite and do not distinguish the claimed product over the prior art.

The following rejections are maintained:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 is drawn to a method of claim 13, "wherein satiety and satiation are induced while lowering a caloric content." The limitation is indefinite because it is unclear which caloric content or glycemic index is lowered. Does the lowered caloric content and glycemic index refer to the food composition recited in claim 13? If so, it is unclear what the food composition is being compared to.

"Lowered" is a relative term. The food composition is lower in caloric content/glycemic index compared to what?

The following rejections are maintained:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 15-27, 29, 32, 34, 35, 41, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Geel-Schutten et al. (Applied and Environmental Microbiology, 1999, pp. 3008-3014, Vol. 65(7), PTO-1449 submitted September 4, 2007).

Van Geel-Schutten et al. teach that polysaccharides are used as viscosifying, stabilizing, emulsifying, gelling, or water-binding agents in food industries, and that exopolysaccharides (EPS) produced from lactic acid bacteria are particularly desirable as food additives because lactic acid bacteria are food-grade organisms with GRAS status [page 3008, first paragraph]. Lactic acid bacteria and EPS contribute to the taste, smell, texture, and preservation of fermented milk products [page 3008, second paragraph]. EPS from lactic acid bacteria may be used as food-grade polysaccharides. One such EPS is produced from sucrose by the action of *Lactobacillus reuteri* [page 3008, third paragraph] (a preferred embodiment referred to as reuteran on page 5 of the

instant specification). The glucan consists of terminal, 4-substituted, 6-substituted, and 4,6-disubstituted alpha-glucose in a molar ratio of 1.1 : 2.7 : 1.5 : 1.0 , indicating the presence of a branched glucan [page 3010, third paragraph].

Van Geel-Schutten et al. do not explicitly teach a food composition comprising reuteran or the administration of such.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a food composition comprising reuteran and to administer that composition to a subject. The person in need of satiety and satiation is interpreted to be a person who is not full or a person who is hungry. Thus, the claims are interpreted as a method which comprises administering a food product comprising alpha-glucan to a hungry person in order to induce satiety or fullness. Administration of a food product to a hungry person flows logically, and the claimed alpha-glucans are known to be food additives which can improve the properties of foods. Thus, it would be obvious to incorporate reuteran into a food product and administer that product to a hungry person.

Van Geel-Schutten teaches the desirability of EPS produced by lactic acid bacteria (of which reuteran is one) as food-grade polysaccharide additives. Van Geel-Schutten suggests a food product; the administration of a food product to induce satiety flows logically. It is within the skill of the skilled artisan to optimize the amount of reuteran for the desired taste, smell and texture. The claims require a food composition whose texture is not substantially changed by addition of alpha-glucan, but it is unclear which foods meet that limitation and how much reuteran can be added without changing

the texture, as set forth above. Because Van Geel-Schutten suggests EPS molecules for enhancing taste, smell, preservation, or other qualities for which high-molecular-weight polysaccharides are used in food products, the skilled artisan would be motivated to prepare food products containing reuteran for those reasons, and to administer a food product to a subject in need of satiety flows logically.

Van Geel-Schutten et al. do not address the viscosity of aqueous solutions of glycogen at pH 6.8 and pH 2. However, this is an intrinsic property of reuteran. Further, Van Geel-Schutten et al. suggest the use of polysaccharides as viscosifying agents.

### ***Response to Arguments***

Applicant argues that reuteran contributes to the texture of fermented milk, and that the instant claims require administration of a food product whose texture is not changed by addition of alpha-glucan. As set forth above, it is unclear which food products are encompassed by the claims, but Van Geel-Schutten's teachings of improved taste and texture and preservation are properties that are desirable in foods generally.

Applicant argues that Van Geel-Schutten is non-analogous prior art because the reference does not mention inducing satiety or satiation. This argument is not persuasive because Van Geel-Schutten teaches EPS as a food additive which contributes positively to taste and smell of food. As set forth above, administration of a food product to a hungry person flows logically, and a food product which has a good taste and smell would be especially preferred by the hungry person.



For these reasons, the rejection is maintained.

Claim 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Geel-Schutten et al. as applied to claims 13, 21-23, 15-19, 27, 41, 29, 24-26, 32, 34, 20, and 35 above, and further in view of Pucci et al. (US 4,877,634, October 31, 1989, of record).

Van Geel-Schutten et al. teach as set forth above, but are silent regarding caloric content and glycemic index of products comprising reuteran.

Pucci et al. teach polysaccharides produced by the fermentation of sucrose, which are useful for improving the texture, stability, or thickness of foods [see abstracts]. The polysaccharides were used as thickeners for milk drinks [column 6, Example 7] or ice cream or frozen yogurt [columns 7 and 8, Example 9]. The ice cream preparation had fewer calories as a result of replacing some of the whipping cream and milk with the thickener. Claims 44 and 45 are vague and indefinite, as set forth above. However, if the claims are intended to drawn to manipulation of calories and glycemic index of foods by addition of reuteran, it would be obvious for the skilled artisan to do that. Pucci teaches that replacement of whipping cream and milk with polysaccharides produced from fermentation of sucrose results in ice cream with fewer calories. The skilled artisan would also understand that removal of carbohydrate calories would very likely lower the glycemic index of a given food. Because reuteran was taught to be useful as a food additive for similar uses as Pucci's polysaccharide and because Pucci's

polysaccharide is also prepared from fermentation of sucrose, as is reuteran, the skilled artisan could reasonably expect similar effects using either.

***Response to Arguments***

Applicant argues that Pucci's polysaccharides are different from reuteran, and so there is no reasonable expectation that they would have the same properties. This argument is not persuasive because Pucci teaches the use of polysaccharides produced by the fermentation of sucrose for improving texture, stability, or thickness of foods. Van Geel-Schutten also suggests the use of EPS as viscosifying or stabilizing additives, and also for improving the texture of foods. Thus, Pucci and Van Geel-Schutten both teach high molecular weight polysaccharides, produced by fermentation of sucrose, for the same purposes. Because they are useful for the same purposes, the skilled artisan would have a reasonable expectation that Van Geel-Schutten's products could be used in the same way as Pucci's products.

Claims 15, 16, 18-20, 24, 29, 32-34, 36-40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote et al. (US 5,786,196, July 28, 1998, of record) in view of Ritchey et al. (US 5,688,547, November 18, 1997, of record).

Cote et al. teach that high-molecular weight alternan consists primarily of  $\alpha$ -1,3-linked and  $\alpha$ -1,6-linked glucose residues with approximately 10% branching [column 1, lines 10-17]. Alternan is synthesized from sucrose via the enzyme alternan-sucrase [column 1, lines 23-24]. Alternan has potential as a substitute for gum arabic and for

use as a bulking agent in foods, particularly as noncaloric, carbohydrate-based soluble food additives in artificially sweetened foods [column 1, lines 34-39].

Cote et al. do not exemplify a food composition comprising alternan.

Ritchey et al. teach an artificially sweetened meal replacement composition [see abstract], which comprises dietary fiber such as guar gum in an amount of 1-66% by weight, and 4-86% by weight of protein [column 4, lines 24-64]. In one example, gum arabic was used at 6.25% and whey protein concentrate at about 12% [column 5, Example 1]. The composition can be used as a shake or a mousse to induce satiety [see abstract].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a food composition comprising alternan and at least 1 wt% of a food protein and to administer the composition. Cote et al. suggest the use of alternan as an alternative to gum arabic and an additive to artificially sweetened foods. Ritchey et al. teach one example of an artificially sweetened food which comprises gum arabic. Thus, the skilled artisan could conceive of replacing the gum arabic in Ritchey's composition with alternan and administering the composition.

### ***Response to Arguments***

Applicant argues that Cote is directed to products which have a low average molecular weight, which does not meet the limitation  $10^5$  Da. Indeed, portions of the Cole reference refer to low-molecular weight fractions. However, the reference teaches that "high-molecular weight alternan may be produced," and "this compound," as well as low-molecular weight products produced therefrom, "lend themselves to potential

commercial applications as substitutes for gum arabic, for use as bulking agents and extenders in foods and cosmetics, particularly as noncaloric, carbohydrate-based soluble food additives in artificially sweetened foods." [column 1, lines 24-39] Thus, Cole teaches the benefits of both the high-molecular weight alternan and the low-molecular weight alternan.

Applicant's argument regarding the texture of the food composition is substantially the same as set forth above. The cited references suggest replacement of gum arabic with alternan. Because alternan is taught as a replacement for gum arabic, the skilled artisan could expect that the replacement would not substantially change the texture of the composition. Furthermore, the metes and bounds of the claimed food composition are unclear, as set forth above.

For these reasons, the rejection is maintained.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1623

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